AUG 1 4 2001

K010118

510 (k) Summary

Device Name:
Normed Mandibular Fixation System

Device Identification:
Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Class II

Product Code:
OR(87)HRS

The Normed Mandibular Fixation System consists of a series of plates and screws in varying configurations and lengths, which are attached to the bone using screw fixation. The plates are available in two system namely, 2.3 system with 1.5mm plate thickness and 2.7 system with 2.0 and 2.2 mm plate thickness. Additionally, there are two screw diameters of 2.3 and 2.7 mm. The emergency screws are 2.7 and 3.0 mm diameters.

The Normed Mandibular Fixation System is intended for use in selective trauma or for reconstructive procedures in the mandible. Specifically, the device is indicated for use in surgical repair procedures in the treatment of trauma to the mandible and in reconstructive procedures of the mandible. The system can be used in both adult and pediatric patients.

The substantial equivalence of these devices is based on equivalence in intended use, design, materials and operating principals to several legally marketed devices including the KLS- Martin Mandibular Fracture/Reconstruction System.

Official Contact Person:
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Paramus, NJ 07652
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2001

Mr. Albert Enayati
President
Osteomedics Incorporated
809 Carter Lane
Paramus, New Jersey 07652

Re: K010118
Trade/Device Name: Normed Mandibular Fixation System
Regulation Number: 872.4760
Regulatory Class: II
Product Code: JEY
Dated: May 31, 2001
Received: June 4, 2001

Dear Mr. Enayati:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510 (k) Number (if known): K010118

Device Name: Normed Mandibular Fixation System

Indications for use:

The Normed Mandibular Fixation System is intended for use in selective trauma or for reconstructive procedures in the mandible. Specifically, the device is indicated for use in surgical repair procedures in the treatment of trauma to the mandible, and in reconstructive procedures of the mandible. The Normed Mandibular Fixation System stabilizes bone during healing in conjunction with appropriate postoperative immobilization. The use is in both adult and pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription use ✓ OR OVER – THE – COUNTER USE_____

(Per 21 CFR 801.109)

for MSR

Gerald W Shipman

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010118

(Optional Format 1-2-96)